Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 255

Report Date:04/29/2009

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Southern Research Institute Southern Research Institute Southern Research Institute Southern Research Institute	052011407 059601905 059601705 059601505	10/02/02 09/26/01 03/08/00 09/05/01	730 729 729 729	50 (3) 50 (3) 50 (3) 50 (3)	28(696) 31(686) 34(683) 31(692)	532.4 526.0 522.9 507.8	Sodium dichromate dihydrate (VI) Water disinfection byproducts (Bromochloroacetic acid) Water disinfection byproducts (Dibromoacetic acid) Water disinfection byproducts (Dibromoacetonitrile)
				Fen	nale		
Southern Research Institute Southern Research Institute Southern Research Institute Southern Research Institute	052011407 059601905 059601705 059601505	10/02/02 09/26/01 03/08/00 09/05/01	735 731 734 734	50 (5) 50 (5) 50 (5) 50 (5)	33(700) 34(688) 35(693) 29(689)	351.2 357.3 350.5 337.6	Sodium dichromate dihydrate (VI) Water disinfection byproducts (Bromochloroacetic acid) Water disinfection byproducts (Dibromoacetic acid) Water disinfection byproducts (Dibromoacetonitrile)

ay2009 Toxic

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 256

			Male				Female	
#All Organs: Benign Tumors								
		49/50 (98%) 50/50 (100%)	50/50 (100%)	47/50 (94%)		47/50 (94%) 44/50 (88%)	49/50 (98%)	42/50 (84%)
Overall Incidence	Total	196/200 (98%)	Mean 98%	SD 2.83%	Total	182/200 (91%)	Mean 91%	SD 6.22%
#All Organs: Malignant Tumors								
-		29/50 (58%) 27/50 (54%)	27/50 (54%)	29/50 (58%)		20/50 (40%) 20/50 (40%)	18/50 (36%)	16/50 (32%)
Overall Incidence	Total	112/200 (56%)	Mean 56%	SD 2.31%	Total	74/200 (37%)	Mean 37%	SD 3.83%
#All Organs: Malignant and Benign T					•••••			
		50/50 (100%) 50/50 (100%)	50/50 (100%)	50/50 (100%)		49/50 (98%) 48/50 (96%)	49/50 (98%)	45/50 (90%)
Overall Incidence	Total	200/200 (100%)	Mean 100%	SD 0%	Total	191/200 (95.5%)	Mean 95.5%	SD 3.79%
#All Organs: Hemangioma					•••••			
· ·		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #All Organs: Hemangiosarcoma or Hemangioma 1/50 (2%)0/50 (0%)(2%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 1/50 (2%)2/200 (1%) **Overall Incidence** Total Mean 1% SD 1.15% Total 1/200 (0.5%) Mean 0.5% SD 1% #All Organs: **Histiocytic Sarcoma** 0/50 (0%)0/50 (0%)0/50 (0%)(2%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/200 (1%) Mean 1% SD 2% Total 1/200 (0.5%) Mean 0.5% SD 1% #All Organs: Leukemia: Erythrocytic 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/200 (0%) Mean 0% Total 0/200 (0%) Mean 0% #All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated 26/50 (52%)21/50 (42%)17/50 (34%)8/50 (16%)15/50 (30%)11/50 (22%)21/50 (42%)14/50 (28%)**Overall Incidence** 85/200 (42.5%) SD 7.37% 48/200 (24%) Total Mean 42.5% Total Mean 24% SD 6.32% **#All Organs:** Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** 0/200 (0%) SD 0% Mean 0.5% SD 1% Total Mean 0% Total 1/200 (0.5%)

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: RATS Strain: F344 Route: ORAL Vehicle: WATER

			Male				Female	
All Organs: Mesothelioma: Benign								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Benign, Ma								
.	g ,	2/50 (4%) 0/50 (0%)	1/50 (2%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	6/200 (3%)	Mean 3%	SD 2.58%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Malignant	•••••				•••••			
•		2/50 (4%) 0/50 (0%)	1/50 (2%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	6/200 (3%)	Mean 3%	SD 2.58%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 259
Report Date: 04/29/2009

Species: RATS Strain: F344 Route: ORAL Vehicle: WATER

			Male				Female	
All Organs: Osteosarcoma or Osteoma		0/50 /00/	0/50 /00/	0/50 (00/)		0/50 /00/	4/50 (20/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Adrenal Cortex: Adenoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%
Adrenal Cortex: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
drenal Medulla: Ganglioneuroma								
v		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Hemangioma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male				Female	
*Adrenal Medulla: Pheochromocytoma Bei	nign							
	_	6/49 (12%) 10/50 (20%)	9/50 (18%)	7/49 (14%)		2/49 (4%) 1/49 (2%)	2/49 (4%)	1/49 (2%)
Overall Incidence	Total	32/198 (16.16%)	Mean 16.13%	SD 3.51%	Total	6/196 (3.06%)	Mean 3.06%	SD 1.18%
*Adrenal Medulla: Pheochromocytoma Co							•••••	
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Ma								
·		1/49 (2%) 0/50 (0%)	1/50 (2%)	0/49 (0%)		1/49 (2%) 0/49 (0%)	2/49 (4%)	0/49 (0%)
Overall Incidence	Total	2/198 (1.01%)	Mean 1.01%	SD 1.17%	Total	3/196 (1.53%)	Mean 1.53%	SD 1.95%
Adrenal Medulla:	mian Complex	Malianant NOS						
Pheochromocytoma: Be	ingn, complex	7/49 (14%) 10/50 (20%)	10/50 (20%)	7/49 (14%)		3/49 (6%) 1/49 (2%)	4/49 (8%)	1/49 (2%)
Overall Incidence	Total	34/198 (17.17%)	Mean 17.14%	SD 3.3%	Total	9/196 (4.59%)	Mean 4.59%	SD 3.06%
#Bone: Chondrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 261

			Male				Female	
Bone: Chondrosarcoma or Chondr	oma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Bone: Chordoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Bone: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Brain: Astrocytoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Ependymoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Ependymoma Malignant	•••••							
. ,		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Glioma Malignant							•••••	
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Benigi								
g.		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 263

			Male				Female	
Brain: Medulloblastoma Mal		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	,	,		0/50 (0%)	,	,
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Brain: Meningioma: Benign, Mali	gnant, NOS	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Brain: Oligodendroglioma Benig	n							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Maligr								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 264 Report Date: 04/29/2009

Species: RATS Strain: F344 Route: ORAL Vehicle: WATER

			Male				Female	
Brain:								
Oligodendroglioma, Gli	ioma, or Astroc	•						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Osteosarcoma	•••••		•••••			•••••		•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Schwannoma Malignan	nt							
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma	•••••							
		4/50 (8%) 1/48 (2%)	4/50 (8%)	3/50 (6%)		2/50 (4%) 5/50 (10%)	17/50 (34%)	8/50 (16%)
Overall Incidence	Total	12/198 (6.06%)	Mean 6.02%	SD 2.79%	Total	32/200 (16%)	Mean 16%	SD 12.96%
Clitoral/Preputial Gland: Carcinoma	•••••							
		1/50 (2%) 0/48 (0%)	2/50 (4%)	0/50 (0%)		8/50 (16%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/198 (1.52%)	Mean 1.5%	SD 1.91%	Total	10/200 (5%)	Mean 5%	SD 7.39%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 265

			Male				Female	
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		4/50 (8%) 1/48 (2%)	5/50 (10%)	3/50 (6%)		10/50 (20%) 6/50 (12%)	17/50 (34%)	9/50 (18%)
Overall Incidence	Total	13/198 (6.57%)	Mean 6.52%	SD 3.38%	Total	42/200 (21%)	Mean 21%	SD 9.31%
*Clitoral/Preputial Gland: Fibrosarcoma								
		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Sarcoma								
		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/50 (0%) 0/48 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Ear: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Esophagus: Fibrosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Esophagus: Lipoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Eye: Amelanotic Melanoma, Ben		0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Eye: Melanoma Malignant Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Eye: Schwannoma Malignant		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: WATER

			Male				Female	
#Harderian Gland: Carcinoma		0/50 (00)	(00)	2/72 (224)		2/20 (20)	2/22 (22)	2/72 (221)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign				•••••				
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%
*Heart: Schwannoma Malignant					•••••			
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Large: Colon/Rectur								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 268

			Male				Female	
#Intestine Large: Colon/Re Carcinoma	ctum:							
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Large: Colon/Re Carcinoma or Adenoma	ctum:					•••••		
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Large: Colon/Re Hemangioma					•••••			
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenui Carcinoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenui Leiomyoma						•••••		
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incider

Species: RATS
Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 269

			Male				Female	
#Intestine Small: Jejunum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Granular Cell Tumor Ma							•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma					•••••			
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma					•••••			
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Small: Site Unsp Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female	
Intestine Small: Site Unsp Carcinoma or Adenom								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unsp Granular Cell Tumor M								
	_	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unsp Leiomyoma	pecified:				•••••			
,		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
ntestine Small: Site Unsp Leiomyosarcoma	pecified:							
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
slets, Pancreatic: Adenoma					•••••			
		4/50 (8%) 5/49 (10%)	3/50 (6%)	5/48 (10%)		2/50 (4%) 1/50 (2%)	3/49 (6%)	0/47 (0%)
Overall Incidence	Total	17/197 (8.63%)	Mean 8.66%	SD 2.08%	Total	6/196 (3.06%)	Mean 3.03%	SD 2.63%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Islets, Pancreatic: Carcinoma 0/50 (0%)(4%)(0%)0/50 (0%)0/49 (0%)(0%)(0%)1/49 (2%)0/50 **Overall Incidence** Total 3/197 (1.52%) Mean 1.51% SD 1.92% Total 0/196 (0%) Mean 0% SD 0% *Islets. Pancreatic: Carcinoma or Adenoma 4/50 (8%)(10%)(10%)2/50 (4%)(0%)6/49 (12%)1/50 (2%)**Overall Incidence** Total 20/197 (10.15%) Mean 10.17% SD 1.74% Total 6/196 (3.06%) Mean 3.03% SD 2.63% *Kidney: Pelvis and Transitional Epithelium: Carcinoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/49 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/198 (0%) Mean 0% Total 0/200 (0%) Mean 0% *Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** 0/198 (0%) SD 0% SD 0% Total Mean 0% Total 0/200 (0%) Mean 0% *Kidney: Pelvis and Transitional Epithelium: **Papilloma** 0/50 (0%)0/50 (0%)0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/198 (0%)Mean 0% SD 0% Total 0/200 (0%)Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

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			Male				Female	
Kidney: Renal Tubule: Adenoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Kidney: Renal Tubule: Carcinoma			•••••					•••••
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma			•••••					•••••
		0/50 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Lipoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

1. Way2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Report Date:04/29/2009

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			Male				Female	
*Kidney: Renal Tubule: Mesenchymal Tumor Ber	nign							
-		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma	•••••							
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma	•••••				•••••			
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Cholangioma	•••••				•••••			
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hemangiosarcoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

d Control Animal Groups Report Date:04/29/2009
RAL

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			Male				Female	
*Liver: Hepatocellular Adenoma								
		0/50 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
*Liver: Hepatocellular Carcinoma	1	•••••			•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma	or Hepatob	lastoma 0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma	or Hepatoc	0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/50 (0%) 3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/50 (0%) 3/200 (1.5%)	Mean 1.5%	SD 1.91%
*Liver: Hepatocellular Carcinoma Hepatoblastoma	a, Hepatocell	ular Adenoma, or						
···opatooiaotoiiia		0/50 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Lung: Alveolar/Bronchiolar Adenoma 4/50 (8%)(4%)(4%)4/50 (8%)(2%)(2%)(6%)3/50 1/50 (2%)**Overall Incidence** Total 11/200 (5.5%) Mean 5.5% SD 1.91% Total 7/200 (3.5%) Mean 3.5% SD 3% *Lung: Alveolar/Bronchiolar Carcinoma 0/50 (0%)(0%)0/50 (0%)0/50 (0%)(2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 2/200 (1%) SD 1.15% Total Mean 0.5% SD 1% Mean 1% 1/200 (0.5%) *Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma (8%)3/50 (4%)4/50 (8%)1/50 2/50 (4%)(8%) (2%) 4/50 1/50 **Overall Incidence** Total 13/200 (6.5%) SD 1.91% 8/200 (4%) SD 2.83% Mean 6.5% Total Mean 4% *Lung: Fibrosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)SD 0% 0/200 (0%) SD 0% **Overall Incidence** Total 0/200 (0%) Mean 0% Total Mean 0% *Lung: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Lung: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Lung: Squamous Cell Carcinoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenolipoma	•••••				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Species: RATS Strain: F344 Route: ORAL Vehicle: WATER

			Male				Female	
Mammary Gland: Carcinoma								
		1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 2/50 (4%)	1/50 (2%)	3/50 (6%)
verall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	6/200 (3%)	Mean 3%	SD 2.58%
Mammary Gland: Carcinoma or Adenoma							•••••	
		1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%) 2/50 (4%)	1/50 (2%)	3/50 (6%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	8/200 (4%)	Mean 4%	SD 1.63%
Mammary Gland: Fibroadenoma								
		2/50 (4%) 6/50 (12%)	3/50 (6%)	4/50 (8%)		37/50 (74%) 31/50 (62%)	43/50 (86%)	32/50 (64%)
overall Incidence	Total	15/200 (7.5%)	Mean 7.5%	SD 3.42%	Total	143/200 (71.5%)	Mean 71.5%	SD 11%
Mammary Gland: Fibroma							•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenoma or								
		2/50 (4%) 6/50 (12%)	3/50 (6%)	4/50 (8%)		37/50 (74%) 31/50 (62%)	43/50 (86%)	32/50 (64%)
Overall Incidence	Total	15/200 (7.5%)	Mean 7.5%	SD 3.42%	Total	143/200 (71.5%)	Mean 71.5%	SD 11%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

(0%)

(0%)

(0.5%)

0/50

(0%)

Mean 0.5%

0/50

0/50

1/200

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male Female #Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma (6%)(6%)(10%)(74%)(86%)(64%)6/50 (12%)31/50 (62%)**Overall Incidence** 17/200 (8.5%) Mean 8.5% SD 3% Total 143/200 (71.5%) Mean 71.5% SD 11% Total #Mesentery: Fibrosarcoma 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% Total #Mesentery: Hemangiosarcoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/200 (0%) Mean 0% Total 0/200 (0%) Mean 0% #Mesentery: Lipoma 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/200 (0%) SD 0% SD 0% Total Mean 0% Total 0/200 (0%) Mean 0% #Mesentery:

SD 1%

0/50

0/50

0/200

Total

(0%)

(0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

Rhabdomyosarcoma

Overall Incidence

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Vehicle: WATER

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date:04/29/2009

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Species: RATS Strain: F344

Length of Study: CHRONIC

			Male	Female
*Nose: Adenoma		0/50 (00/)	0/50 (00/) 0/40 (00/)	0/50 (00) 0/50 (00)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
*Nose: Chondroma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
*Nose: Squamous Cell Carcinor	 ma			
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
#Oral Cavity (Oral Mucosa, 7 Papilloma Squamous or	Tongue, Phary			
	·	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%) 0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 3/200 (1.5%) Mean 1.5% SD 1%
#Oral Cavity (Oral Mucosa, 7 Squamous Cell Carcinor		nx, Tooth, Gingiva):		
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Mean 0%

SD 0%

Report Date: 04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or **Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)1/50 1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** SD 0% 3/200 (1.5%) Mean 1.5% SD 1% Total 0/200 (0%) Mean 0% Total **#Oral Mucosa:** Squamous Cell Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) (0%)0/50 0/50 0/200 (0%) SD 0% 0/200 (0%) SD 0% Overall Incidence Total Mean 0% Total Mean 0% **#Oral Mucosa: Squamous Cell Papilloma** (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%) (0%) 0/50 0/50 **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% *Ovary: Cystadenoma 0/49 0/50 (0%)0/50 (0%)0/50 (0%)SD 0% **Overall Incidence** Total 0/199 (0%) Mean 0% *Ovary: **Granulosa Cell Tumor Benign** 0/490/50 (0%)0/50 (0%)0/50 (0%)

Total

0/199 (0%)

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

	Male			Female	
*Ovary:					
Granulosa Cell Tumor Malignant		0/4	9 (0%)	0/50 (0%)	0/50 (0%)
	_	0/5	, ,		
Overall Incidence	To	tal 0/199	9 (0%)	Mean 0%	SD 0%
*Ovary:					
Granulosa Cell Tumor: Benign, Malignant, NOS		0/4	0 (00()	0/50 (00/)	0/50 (00/)
		0/4 0/5		0/50 (0%)	0/50 (0%)
Overall Incidence	To		0%)	Mean 0%	SD 0%
*Overv			•••••		
*Ovary: Granulosa-Theca Tumor Benign					
Č		0/4		0/50 (0%)	0/50 (0%)
Overall Incidence	To	1/5 1/100 let	0 (2%)	Mean 0.5%	SD 1%
*Ovary:					
Granulosa-Theca Tumor Malignant		0/4	9 (0%)	0/50 (0%)	0/50 (0%)
		0/5		0/30 (0/0)	0/00 (0/0)
Overall Incidence	To	tal 0/199	9 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma					
rabalosti oniai Adenoma		0/4		0/50 (0%)	0/50 (0%)
Occupation of the con-		0/5	, ,	M 00/	OD 00/
Overall Incidence	To	tal 0/199	9 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 282

			Male				Female	
Pancreas: Adenoma		1/50 (2%)	2/50 (4%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/47 (0%)
		1/49 (2%)	2/30 (4%)	0/46 (0%)		0/50 (0%)	0/30 (0%)	0/47 (0%)
Overall Incidence	Total	4/197 (2.03%)	Mean 2.01%	SD 1.63%	Total	0/197 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma								
		1/50 (2%) 1/49 (2%)	2/50 (4%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	4/197 (2.03%)	Mean 2.01%	SD 1.63%	Total	0/197 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Benign								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Malignant								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 283

			Male				Female	
Parathyroid Gland: Adenoma								
		0/46 (0%) 1/46 (2%)	0/44 (0%)	0/50 (0%)		0/46 (0%) 0/42 (0%)	0/42 (0%)	0/50 (0%)
Overall Incidence	Total	1/186 (0.54%)	Mean 0.54%	SD 1.09%	Total	0/180 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma Malignant			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign, Ma	lignant, NOS	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis Adenoma								
		16/50 (32%) 24/50 (48%)	23/48 (48%)	23/50 (46%)		28/50 (56%) 27/49 (55%)	28/50 (56%)	26/50 (52%)
Overall Incidence	Total	86/198 (43.43%)	Mean 43.48%	SD 7.71%	Total	109/199 (54.77%)	Mean 54.78%	SD 1.9%
Pituitary Gland: Pars Distalis Carcinoma					•••••			
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		2/50 (4%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	2/199 (1.01%)	Mean 1%	SD 2%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male		Female						
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma											
		16/50 (32%) 24/50 (48%)	23/48 (48%)	23/50 (46%)		30/50 (60%) 27/49 (55%)	28/50 (56%)	26/50 (52%)			
Overall Incidence	Total	86/198 (43.43%)	Mean 43.48%	SD 7.71%	Total	111/199 (55.78%)	Mean 55.78%	SD 3.3%			
Pituitary Gland: Pars Dista Ganglioneuroma	lis or Unspecif	ied Site:									
-		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%			
Pituitary Gland: Pars Interr Adenoma	media:										
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	1/50 (2%)			
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%			
Pituitary Gland: Pars Interr Carcinoma	media:										
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)			
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%			
Pituitary Gland: Pars Interr Carcinoma or Adenoma	media:										
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%			

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Toxicology Data Management System

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 285

			Male				Female	
Prostate:								
		2/50 (4%) 0/49 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%				
Prostate: Carcinoma or Adenoma								
		2/50 (4%) 0/49 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%				
Salivary Glands: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				
Skeletal Muscle: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male				Female				
#Skeletal Muscle: Hemangioma											
ū		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%			
Skeletal Muscle: Hemangiosarcoma											
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%			
#Skeletal Muscle: Lipoma	•••••										
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%			
Skeletal Muscle: Rhabdomyosarcoma						•••••	•••••				
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%			
#Skeletal Muscle: Rhabdomyosarcoma or I						•••••					
,		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female				
Skeletal Muscle: Sarcoma 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50											
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%			
Skin: Basal Cell Adenoma							•••••				
		2/50 (4%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.31%	Total	0/200 (0%)	Mean 0%	SD 0%			
Skin: Basal Cell Adenoma or B Overall Incidence	Basosquamou Total	s Tumor Benign 2/50 (4%) 2/50 (4%) 4/200 (2%)	0/50 (0%) Mean 2%	0/50 (0%) SD 2.31%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Skin: Basal Cell Adenoma, Bas Trichoepithelioma						,					
·		2/50 (4%) 2/50 (4%)	3/50 (6%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
verall Incidence	Total	8/200 (4%)	Mean 4%	SD 1.63%	Total	0/200 (0%)	Mean 0%	SD 0%			
Skin: Basal Cell Carcinoma											
		0/50 (0%) 2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

				Male						Fema	ie		
Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)													
1100)			0%) 4%))/50 (0%)) 1/50	(2%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	3/200 (1.5	,	Mean 1.5		1.91%	Total	0/200	` ,	Mean		SD	
#Skin: Basal Cell Carcinoma, Tumor (benign, maligr	Basal Cell Ader	noma, Basosqu Trichoepithelio	uamous oma	3/50 (6%		(4%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		4/50 (8%)́		,	,		0/50	(0%)		,		,
Overall Incidence	Total	11/200 (5.	5%)	Mean 5.5	% SD	1.91%	Total	0/200	(0%)	Mean	0%	SD	0%
#Skin: Basal or Sq. Cell Carci or B), Basal Cell Aden Papilloma, Keratoacan	oma, Adenoma,	Papilloma, Sq pithelioma	•	NEO (400	() 7/50	(4.40/.)		4/50	(20()	0/50	(00()	4/50	(20()
Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan	oma, Ådenoma, nthoma, Trichoe	Papilloma, Sq pithelioma 5/50 (11/50 (10%) 6 22%)	6/50 (12%	,	(14%)	Total	1/50 0/50	(2%) (0%)	0/50 Maga	(0%)	1/50	(2%)
Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence	oma, Ådenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 5/50 (11/50 (; 29/200 (14	10%) 6 22%) 4.5%)	Mean 14.	5% SD	5.26%	Total	0/50 2/200	(0%) (1%)	Mean	1%	SD	1.15%
Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence	oma, Ådenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 5/50 (11/50 (29/200 (14	10%) 6 22%) 4.5%)	Mean 14.	5% SD	5.26%		0/50 2/200	(0%) (1%)	Mean	1%	SD	1.15%
Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence	oma, Ådenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 5/50 (11/50 (29/200 (14	10%) 6 22%) 4.5%)	Mean 14.	5% SD	5.26%		0/50 2/200	(0%) (1%)	Mean	1%	SD	1.15%
Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence #Skin: Fibroma	oma, Ádenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 5/50 (11/50 (3 29/200 (14 8/50 (8/50 (28/200 (14	10%) 6 22%) 4.5%)	Mean 14.4 7/50 (14% Mean 14%	5% SD 6) 5/50 6 SD	5.26% (10%) 2.83%	Total	0/50 2/200 1/50 0/50 3/200	(0%) (1%) (2%) (0%) (1.5%)	Mean 1/50 Mean	1% (2%) 1.5%	1/50 SD	1.15% (2%) 1%
or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence *Skin: Fibroma	oma, Ádenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 5/50 (11/50 (29/200 (14 8/50 (8/50 (28/200 (14	10%) 6 22%) 4.5%)	Mean 14.4 7/50 (14% Mean 14%	5% SD 6) 5/50 6 SD	5.26% (10%) 2.83%	Total	0/50 2/200 1/50 0/50 3/200	(0%) (1%) (2%) (0%) (1.5%)	Mean 1/50 Mean	1% (2%) 1.5%	1/50 SD	1.15% (2%) 1%
Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence #Skin: Fibroma Overall Incidence #Skin: Fibroma	oma, Ádenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 5/50 (11/50 (; 29/200 (14 	10%) 6 22%) 4.5%) 16%) 7 16%) 4%)	Mean 14.4 7/50 (14% Mean 14%	5% SD (6) 5/50 (6 SD	5.26% (10%) 2.83%	Total	0/50 2/200 1/50 0/50 3/200	(0%) (1%) (2%) (0%) (1.5%)	Mean 1/50 Mean	1% (2%) 1.5%	1/50 SD	1.15% (2%) 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

I Animal Groups Report Date:04/29/2009

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			Male				Female				
#Skin: Fibrosarcoma											
		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%			
#Skin: Fibrosarcoma, Sarcoma Histiocytoma											
Histocytoma		3/50 (6%) 1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%			
#Skin: Fibrous Histiocytoma			- 1								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%			
#Skin: Hemangioma		(22)	(201)	(50)		2/22 (22)	0.70	2/22 (221)			
		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%			
#Skin: Hemangiosarcoma											
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 290 Report Date: 04/29/2009

Species: RATS Strain: F344 Route: ORAL Vehicle: WATER

			Male				Female	
Skin:								
Keratoacanthoma		2/50 (4%)	1/50 (2%)	3/50 (6%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	6/50 (12%) 12/200 (6%)	Mean 6%	SD 4.32%	Total	0/50 (0%) 1/200 (0.5%)	Mean 0.5%	SD 1%
Skin:						•••••	•••••	••••
Lipoma		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/30 (0%)	Mean 0%	SD 0%
Skin:						•••••	•••••	••••
Liposarcoma		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin:								
Neural Crest Tumor		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin:							•••••	
Neural Crest Tumor, Ma	lignant	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Neurofibroma or Schwannoma benign 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS) 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) #Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%) 0/50 0/50 **Overall Incidence** Total 0/200 (0%) SD 0% Total 0/200 (0%) SD 0% Mean 0% Mean 0% #Skin: Sarcoma 2/50 (4%)0/50 (0%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 3/200 (1.5%) Mean 1.5% SD 1.91% Total 0/200 (0%) Mean 0% SD 0% #Skin: Schwannoma Benign 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 292 Report Date: 04/29/2009

Species: RATS Strain: F344 Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Skin: Schwannoma Malignant		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinom	a							
		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinom Basosquamous Tumor (n			0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma								
Squamous Cell Fapillollia		1/50 (2%) 1/50 (2%)	3/50 (6%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 1.91%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Squamous Cell Papilloma	or Papillom	a			•••••			
•	·	1/50 (2%)	3/50 (6%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/50 (2%) 7/200 (3.5%)	Mean 3.5%	SD 1.91%	Total	0/50 (0%) 1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma (8%)4/50 (8%)(12%)0/50 (0%)1/50 (2%)7/50 (14%)0/50 (0%)**Overall Incidence** 21/200 (10.5%) SD 1.15% Total Mean 10.5% SD 3% Total 2/200 (1%) Mean 1% Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 3/50 4/50 (8%)(10%)1/50 (2%)0/50 1/50 (2%)7/50 (14%)0/50 (0%)19/200 (9.5%) SD 1.15% **Overall Incidence** Total Mean 9.5% SD 3.42% Total 2/200 (1%) Mean 1% #Skin: Trichoepithelioma 0/50 (0%)3/50 1/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%) 0/50 0/50 **Overall Incidence** Total 4/200 (2%) SD 2.83% 0/200 (0%) SD 0% Mean 2% Total Mean 0% #Skin: Sebaceous Gland: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/200 (0.5%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total Mean 0.5% SD 1% #Skin: Sebaceous Gland: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 294

			Male				Female	
Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Spinal Cord: Astrocytoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spinal Cord: Astrocytoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spinal Cord: Glioma Malignant								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Fibrosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 295

			Male				Female	
*Spleen: Fibrous Histiocytoma		2/22 (221)		2(72 (22))		2/22 (221)		2/1- /22/
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
ŭ		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
*Spleen: Leiomyosarcoma					•••••			
,		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
*Spleen: Sarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 296 Report Date:04/29/2009

			Male				Female	
Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma o Overall Incidence	or Papillon Total	na Squamous 0/50 (0%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	1/50 (2%) SD 1%	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	1/50 (2%) SD 1%
Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Stomach, Glandular: Lipoma							- 1	
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 297

			Male				Female	
#Stomach, Glandular: Sarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Testes: Adenoma								
Overall Incidence	Total	48/50 (96%) 49/50 (98%) 184/200 (92%)	46/50 (92%) Mean 92%	41/50 (82%) SD 7.12%				
		,						
*Thymus: Sarcoma								
		0/48 (0%) 0/43 (0%)	0/49 (0%)	1/49 (2%)		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/189 (0.53%)	Mean 0.51%	SD 1.02%	Total	0/197 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign								
		0/48 (0%) 0/43 (0%)	0/49 (0%)	1/49 (2%)		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/189 (0.53%)	Mean 0.51%	SD 1.02%	Total	0/197 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
		0/48 (0%) 0/43 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/189 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male Female *Thymus: Thymoma NOS 0/48 (0%)0/49 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/43 (0%)0/48 (0%)Mean 0% 0/197 (0%) **Overall Incidence** Total 0/189 (0%) SD 0% Total Mean 0% SD 0% *Thymus: Thymoma: Benign, Malignant, NOS 0/48 (0%)0/50 (0%)(0%)0/43 (0%)0/48 (0%)**Overall Incidence** Total Mean 0.51% SD 1.02% Total 0/197 (0%) Mean 0% SD 0% 1/189 (0.53%) *Thyroid Gland: C-Cell: Adenoma 5/50 (10%)(6%)(12%)8/50 (16%)(12%)(12%)10/49 (20%)6/46 (13%) **Overall Incidence** SD 6.07% Total 24/199 (12.06%) Mean 12.1% Total 26/195 (13.33%) Mean 13.32% SD 1.84% *Thyroid Gland: C-Cell: Carcinoma 1/50 (2%)2/50 (4%)(2%)0/50 (0%)1/49 (2%)0/46 (0%)**Overall Incidence** 4/199 (2.01%) Mean 2.01% SD 0.02% 3/195 (1.54%) SD 1.92% Total Total Mean 1.51% *Thyroid Gland: C-Cell: Carcinoma or Adenoma (12%)6/50 (8%)(14%)10/50 (20%)7/49 (14%)(12%)11/49 (22%)6/46 (13%)**Overall Incidence** Total 28/199 (14.07%) Mean 14.11% SD 6.09% Total 29/195 (14.87%) Mean 14.83% SD 3.57%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories Species: RATS

Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 299

			Male				Female	
Thyroid Gland: Follicular Cell: Adenoma								
		0/50 (0%) 0/49 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%) 1/46 (2%)	0/49 (0%)	0/50 (0%)
verall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	1/195 (0.51%)	Mean 0.54%	SD 1.09%
Thyroid Gland: Follicular Cell: Carcinoma								
		0/50 (0%) 0/49 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/46 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/195 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		0/50 (0%) 0/49 (0%)	3/50 (6%)	1/50 (2%)		0/50 (0%) 1/46 (2%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2%	SD 2.83%	Total	1/195 (0.51%)	Mean 0.54%	SD 1.09%
Tissue NOS: Lipoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Tissue NOS: Paraganglioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F344 Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 300

			Male				Female	
#Tissue NOS: Schwannoma Malignant								
_		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Carcinoma						•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
fTongue: Squamous Cell Carcinoma o	or Papillon	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 2/200 (1%)	Mean 1%	SD 1.15%
Tongue: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Tooth: Adamantinoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F344 Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Female Male #Tooth: Odontoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 Mean 0% **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) SD 0% *Urinary Bladder: Carcinoma 0/50 (0%)(0%)(2%)0/49 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/199 (0%) Mean 0% SD 0% *Urinary Bladder: Carcinoma or Papilloma 0/50 (0%)0/50 (0%)(2%)0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Mean 0.5% SD 1% SD 0% Total 1/200 (0.5%) Total 0/199 (0%) Mean 0% *Urinary Bladder: Hemangiosarcoma 0/50 (0%)0/49 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/200 (0%) SD 0% 0/199 (0%) Mean 0% SD 0% Total Mean 0% Total *Urinary Bladder: Leiomyosarcoma 0/50 (0%)(0%)0/49 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%)Mean 0% SD 0% Total 0/199 (0%)Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date:04/29/2009

Page: 302

Species: RATS Strain: F344

Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Urinary Bladder: Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma						1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/50 (0%) 1/200 (0.5%)	Mean 0.5%	SD 1%
#Uterus: Carcinoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
#Uterus: Deciduoma Benign								
Overall Incidence					Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Hemangioma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 303

Report Date: 04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Hemangiosarcoma 0/50 (0%)(0%)(2%) 1/50 **Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% #Uterus: Leiomyoma 0/50 (0%)(0%)(0%)0/50 (0%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Uterus: Leiomyosarcoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%) **Overall Incidence** Mean 0% SD 0% Total 0/200 **#Uterus: Polyp Stromal** 10/50 (20%)(18%)(8%) 13/50 (26%)**Overall Incidence** 36/200 (18%) Mean 18% SD 7.48% Total **#Uterus:** Sarcoma Stromal (0%) 0/50 (0%)0/50 0/50 (0%)**Overall Incidence** Total 0/200 (0%)Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Sarcoma Stromal or Polyp Stromal (20%)(18%)(8%) 13/50 (26%)**Overall Incidence** Total 36/200 (18%) Mean 18% SD 7.48% #Uterus: Schwannoma Malignant 0/50 (0%)(0%)(0%)1/50 (2%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% #Vagina: Polyp 0/50 (0%)0/50 (0%)(0%)0/50 (0%) **Overall Incidence** SD 0% Total 0/200 (0%) Mean 0% #Vagina: Sarcoma (0%) 0/50 0/50 (0%)0/50 0/50 (0%)**Overall Incidence** Mean 0% SD 0% Total 0/200 (0%) #Zymbal's Gland: Adenoma (0%)(0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%)Mean 0.5% SD 1% Total 0/200 (0%)Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

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			Male			Female	
#Zymbal's Gland: Carcinoma							
Caromonia		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total 2/200 (1%)	Mean 1% SD 1.15%	
#Zymbal's Gland: Carcinoma or Adenoma							
		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total 2/200 (1%)	Mean 1% SD 1.15%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied